

K964050

Jan. 6, 1997

SUMMARY OF SAFETY AND EFFICACY

- A. The submitter's name, address, telephone number, contact person, and date of preparation.

Submitted by Becton Dickinson Vascular Access, 9450 South State Street, Sandy, UT 84070.

Contact: C. J. Welle. Telephone: 801-565-2535. Prepared: December 31, 1996.

- B. The name of the device including trade or proprietary name if applicable, the common or usual name, and the classification name.

Name: Intravascular Catheter

Brand: FIRST MIDCATH™

Common Name: Midline Catheter

Classification Name: Intravascular Catheter (80 FOZ)

- C. An identification of the predicate or legally marketed device to which substantial equivalence is claimed:

Predicate Device: The Becton Dickinson Vascular Access FIRST PICC™ brand catheters.

- D. A description of the device that is the subject of the Premarket Notification submission.

The subject catheter is a short term, single use, intravascular catheter of various French sizes and lengths which is designed to provide access to large veins such as the basilic or cephalic veins. It is inserted into the vascular system through a spittable introducer catheter.

- E. Statement of intended use of the device.

The intended use is to provide access to the vascular system to sample blood or administer drug solutions, blood products, or other fluids intravenously.

- F. A statement of how the technological characteristics compare to those of the predicate or legally marketed device identified in section C above.

The proposed catheter differs from the FIRST PICC™ brand catheter in that it is shorter however, the materials used, the design concept, and the manner in which the catheter is placed are the same.

14